## REMARKS

This responds to the Office Action dated June 29, 2006.

Claims 9, 10, 15, and 21 have been amended; as a result, claims 9-18 and 20-21 are now pending in this application.

The amendment to the specification is supported by originally-filed claim 1. The amendments to claims 9 and 21 to recite that the fibrin and albumin have been removed from the animal plasma are supported by the specification at page 10, full paragraph 3 and at page 13, last paragraph.

*§ 112 Rejection of the Claims*

Claim 10 was rejected under 35 U.S.C. § 112(1) as failing to further limit claim 9. This rejection is respectfully traversed. The amendment to claim 10 to recite that the concentrate contains about 35-50% IgG, which is supported at page 15, lines 11-12, moots this rejection.

Claim 15 was rejected under 35 U.S.C. § 112(2) as not having antecedent basis in claim 14. Claim 15 has been amended to recite that the dispersion [of the concentrate] yields the recited IgG concentration. The immunoglobulin concentrate contains immunoglobulins of different classes, including IgA, IgM, IgG and the like.

Therefore, dissolution of the concentrate at or concentration of 0.375-3% by weight to yield an IgG concentration of about 0.1-0.75% by weight IgG is not an inconsistent recitation. In claim 21, line 6, the term "concentrate" is appropriate, as it is part of the supplement which may contain other water soluble components. See, e.g., page 19. Therefore, withdrawal of this rejection is appropriate and is respectfully requested.

Claims 9-18 and 20-21 were rejected under 35 U.S.C. § 112(1) as containing new matter due to the addition of the negative limitation that the supplement is not provided through the animals feed sources or through a milk replacement. The Examiner takes the position that "Applicant has not pointed out where the support comes from." However, the support was quoted in the last Amendment and occurs at pages 9-10, where the negative implications of administering immunoglobulin in feed formulations or milk replacers is discussed. However,

this recitation has been removed from the claims, as it has unexpectedly been found that the advantageous effects of the water-administered concentrate occur even if the animal is also receiving immunoglobulin through feed. Therefore withdrawal of this rejection is respectfully requested.

*§103 Rejection of the Claims*

Claims 9-18 and 20-21 were rejected under 35 U.S.C. § 103(a) as obvious over Newson et al. (U.S. Patent No. 4,096,244), in view of Yoder (U.S. Pat. No. 5,372,811) and Austin et al. (U.S. Pat. No. 5,143,257). Insofar as this rejection may be maintained with respect to any of the amended claims, it is respectfully traversed.

The Newson et al. patent discloses and claims orally administering to piglets a "feed material" comprising nutrients and immunoglobulins obtained from desalinated spray-dried animal blood serum. The present claims are directed to administering a stable immunoglobulin concentrate is administered to pigs by introducing it into their water source, i.e., the pigs ingest the concentrate when they drink from their water line. On the other hand, Newson et al. consistently teaches that the dried, desalinated serum is mixed with the "feed" or "feed stuff" provided to the pigs, including milk replacers. (see Col. 4, lines 11-15; Col. 5, lines 24-56; and claims 3, 4 and 8). The Examiner is requested to note that the art recognizes that a feed composition is different than a water source in animal husbandry, even if the feed is liquid. As discussed at pages 9-10 of the present specification:

> Previous attempts at decreasing morbidity and mortality in young pigs have focused on the delivery of supplements, including immunoglobulin fortified supplements, via dry feed or milk prior to the weaning period. While moderately successful in reducing morbidity and mortality, these methods have many problems, including the expense and difficulties involved with the administration and use of milk replacers. Further, light-end pigs do not benefit from the use of supplements administered through feed since they will consume primarily water during periods of stress [emphasis added].

See also, page 16.

The discovery that effective amounts of immunoglobulin concentrates reduced in fibrin can be administered to pigs through their water supply is the basis of the presently claimed method, and provides a supplement to the feed-based delivery method disclosed and claimed by Newson et al. (which is further discussed at page 7 of the application). Whether or not the active ingredients of the concentrates are present in the same amounts, it is clear that the presently claimed method is neither suggested nor disclosed by Newson et al. The Examiner agrees that the '244 patent does not disclose administering the immunoglobulin concentrate via the animal's water source, and that it does not disclose that improved weight gain result.

It is respectfully submitted that the secondary references do not remedy the deficiencies of the primary reference, The Yoder '811 patent teaches a spray-dried feed supplement comprising amylase and blood plasma containing "60% albumin and about 40% globulin." Col. 3, lines 18-47. The Examiner is urged to consider that the improved weight gain achieved in pigs fed with the supplement is ascribed by Yoder to spray-drying the amylase with the immunoglobulins, not to the presence of the immunoglobulins in the feed. At Col. 5, lines 27-43, Yoder discloses: "Pigs treated with the spray-dried plasma supplemented with traditional rations experienced approximately the normal weight gain of 240 grams per day...Pigs which received the amylase in combination with animal plasma which was co-dried experienced better daily gain [,] feed intake and feed efficiency than those which merely had the animal plasma by itself..." Of course, in the presently recited concentrates the improved weight gain is caused by the immunoglobulins.

The '357 patent simply describes a mechanical system for introducing a "medication or nutrient" in an animal's drinking water. Applicant does not claim to have invented such a device. There is not disclosure in this patent that would motivate the art worker to administer an immunoglobulin concentrate to an animal in its drinking water, to improve weight gain and growth, while reducing morbidity and morality. Even, assuming arguendo, that it would be *prime facie* obvious to try to administer immunoglobulin concentrates or supplements such as those disclosed by Newson and Yoder, via an animal's water supply because devices such as the Austin et al. dispenser exist, Applicants have disclosed the advantages and difficulties inherent in administering immunoglobulin concentrates via an animal's water supply, and have arrived at a

solution -- removing fibrin from the immunoglobulin containing plasma, thus rendering it miscible with drinking water at useful concentrations -- not disclosed or suggested by the prior art. Both Newson et al. and Yoder disclose concentrates that are administered via conventional feed stuffs or milk replacers. Yoder does not ascribe any growth-promoting effects to the immunoglobulins over regular feeding, but ascribes growth promotion to spray-drying amylase with immunoglobulin protein. See, Col. 2, lines 39-47.

Furthermore, the Examiner is requested to consider the Rule 132 declarations executed by inventor Dr. Eric M. Weaver and by Joy Campbell, experienced animal nutritionists. They are employed by the owner of this application.

Table 1 of Campbell's declaration demonstrates the effect of addition of an immunoglobulin product in the drinking water or in feed, so that similar amounts were ingested by the chickens. When the concentrate was given in water, there was an unexpected improvement in average daily gain over controls (no concentrate) or that observed concentrate was given in feed alone. The combination of concentrate in both feed and water gave no further improvement over the concentrate given in the water alone. This indicates that the effect is not simply due to consumption of an increased amount of plasma.

The Weaver declaration describes the results of administering a plasma concentrate in both water and feed of pigs when the concentration in the feed is pre-optimized. The data summarized on Table 1 lead Weaver to conclude that an unexpected increase (198%) in average daily gain occurred when young pigs receiving feed supplemented with immunoglobulin concentrate <u>also</u> received immunoglobulin concentrate via their water supply. See paragraph 15. The data summarized on Table 2 demonstrated a 100% increase in growth and feed intake when older pigs ingested immunoglobulin concentrate in both feed and water, over feed alone. These results are unexpected and permit ADG and ADFI to be unexpectedly increased to an extent that cannot be achieved by simply increasing the amount of concentrate in the feed.

Therefore, it is respectfully submitted that these results are sufficient to rebut any *prima facie* case of obviousness established by the cited art and withdrawal of this rejection is appropriate and is respectfully requested.

## CONCLUSION

Applicant respectfully submits that the claims have been placed in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6903 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

ERIC M. WEAVER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 3737-6903

Date 9-26-06

By _____
Warren D. Woessner
Reg. No. 30,440

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 26 day of September, 2006.

Paula Sucha
Name

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Signature